COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24-IV-2006
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NOT FOR PUBLICATION

COMMISSION DECISION

of 24-IV-2006

on the renewal of the marketing authorisation for the medicinal product for human use "TARGRETIN - bexarotene", granted by Decision C(2001)818

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 24-IV-2006

on the renewal of the marketing authorisation for the medicinal product for human use "TARGRETIN - bexarotene", granted by Decision C(2001)818

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Ligand Pharmaceuticals UK Ltd, on 27 October 2005, under Article 13(1) of Regulation (EEC) No 2309/93 with a view to the renewal of the marketing authorisation for the medicinal product "TARGRETIN - bexarotene"

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 February 2006,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "TARGRETIN - bexarotene", entered in the Community register of

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).
[2] OJ L 136, 30.4.2004, p. 1
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

medicinal products under No(s) EU/1/01/178/001 and authorised by Commission Decision C(2001)818 of 29 March 2001, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) The marketing authorisation which expires on 2 April 2006 should therefore be renewed.

(3) Ligand Pharmaceuticals UK Ltd submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2001)818 of 29 March 2001.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2001)818 of 29 March 2001 which expires on 2 April 2006 is renewed.

Article 2

Decision C(2001)818 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number Annex (EU numbers affected)

EMEA/H/C/326/N/011 IIIB (EU/1/01/178/001)

EMEA/H/C/326/N/014 IIIB (EU/1/01/178/001)

EMEA/H/C/326/N/12 IIIB (EU/1/01/178/001)

EMEA/H/C/326/N/13 IIIB (EU/1/01/178/001)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Ligand Pharmaceuticals UK Ltd, Innovis House, 108 High Street, Crawley, West Sussex RH10 1BB, UNITED KINGDOM.

Done at Brussels, 24-IV-2006

For the Commission
Günter VERHEUGEN
Vice-President of the Commission